K070819

JUN 25 2007

Summary of Safety and Effectiveness

for Bio-Rad Laboratories, Inc.

VARIANT™ II TURBO Link
Hemoglobin A1c Program

Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:_____.

Submitter:

Bio-Rad Laboratories, Inc.
Clinical Diagnostics Group
4000 Alfred Nobel Drive,
Hercules, California 94547
Phone: (510) 741-5309
FAX: (510) 741-6471

Contact Person:

Jackie Buckley
Regulatory Affairs Representative

Date of Summary Preparation: March 23, 2007

Device Name: VARIANT™ II TURBO Link Hemoglobin A1c Program

Classification Name: Assay, Glycosylated Hemoglobin, 81LCP

Predicate Device(s):

VARIANT™ II TURBO Hemoglobin A1c Program
(k) 040872
Bio-Rad Laboratories, Inc.

VARIANT™ II TURBO Hemoglobin A1c Program run on the VARIANT II TURBO Hemoglobin Testing System with CDM 4.0
(k) 063400
Bio-Rad Laboratories, Inc.

Intended Use:

The Bio-Rad VARIANT™ II TURBO Link Hemoglobin A1c Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high performance liquid chromatography (HPLC).

The VARIANT II TURBO Link Hemoglobin A1c Program is for use with the VARIANT II TURBO Link Hemoglobin Testing System interfaced with an automated sample transport system.

The Bio-Rad VARIANT II TURBO Link Hemoglobin A1c Program is for Professional Use Only.

Indications for Use: Measurement of percent hemoglobin A1c is effective in monitoring long-term glucose control in individuals with diabetes mellitus.

Description of the Device:

The VARIANT II TURBO Link Hemoglobin Testing System uses the principles of high performance liquid chromatography (HPLC). The VARIANT II TURBO Link Hemoglobin A1c Program is based on chromatographic separation of Hemoglobin A1c on a cation exchange cartridge. The reagents in the VARIANT II TURBO Link Hemoglobin A1c Program have the same formulation as the reagents in the VARIANT II TURBO Hemoglobin A1c Program.

Technical Characteristics Compared to the Predicate:

The VARIANT II TURBO Link Hemoglobin A1c Program and the predicate VARIANT II TURBO Hemoglobin A1c Program have the same technical characteristics that are summarized in the table below:

Characteristics	VARIANT II TURBO Link Hemoglobin A1c Program	VARIANT II TURBO Hemoglobin A1c Program (k)040872 and VARIANT II TURBO Hemoglobin A1c Program run with CDM™ 4.0(k) 063400
Analyte Measured: Reported	%Hemoglobin A1c	%Hemoglobin A1c
Intended Use	The Bio-Rad VARIANT II TURBO Link hemoglobin A1c Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high-performance liquid chromatography (HPLC). The VARIANT II TURBO Link Hemoglobin A1c Program is for use with the VARIANT II TURBO Link Hemoglobin Testing System interfaced with an automated sample transport system. The Bio-Rad VARIANT II TURBO link Hemoglobin A1c Program is for Professional Use Only.	The Bio-Rad VARIANT II TURBO Hemoglobin A_{1c} Program is intended for the percent determination of hemoglobin A1c in human whole blood using ion-exchange high performance liquid chromatography (HPLC). The Bio-Rad VARIANT II TURBO Hemoglobin A1c Program is intended for Professional Use Only. For In Vitro Diagnostic Use.
Assay Principle	Cation exchange high performance liquid chromatography	Cation exchange high performance liquid chromatography
Reagents in kit	The reagent formulations are the same as the predicate. In addition Buffer A can be purchased as a separate kit and Buffer B can be purchased individually.	Kit contains Analytical cartridge, Guard cartridge, Buffer A, Buffer B, Wash/Diluent Solution Set (sold separately), Whole Blood Primer, and Calibrator/Diluent Set.

Characteristics	VARIANT II TURBO Link Hemoglobin A1c Program	VARIANT II TURBO Hemoglobin A1c Program (k)040872 and (k) 063400
Sample Type	Human anticoagulated whole blood (EDTA)	Human anticoagulated whole blood (EDTA)
Sample transport mode of operation	Continuous feed, batch or STAT mode of closed EDTA sample tubes from automated sample transport system.	Batch mode of closed EDTA sample tubes
Automated sample transport system	The VARIANT II TURBO Link Hemoglobin Testing System requires an external automated sample transport system such as the Sysmex® HST-N (Hemoglobin Sample Transport) System.	The VARIANT II TURBO Hemoglobin Testing System is complete with an automated sample conveyor system.
Standardization	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP).	Traceable to the Diabetes Control and Complications Trial (DCCT) reference method and IFCC. Certified via the National Glycohemoglobin Standardization Program (NGSP).

Testing To Establish Substantial Equivalence:

Accuracy:

Method correlation between the VARIANT II TURBO Link Hemoglobin A1c Program and VARIANT II TURBO Hemoglobin A1c Program was evaluated using 180 EDTA whole blood patient samples ranging from 4.2% to 14.0% HbA1c. The results are presented in the following regression table.

Regression Method	n	R^2	Slope	Intercept
Least Squares	180	0.998	0.983	0.225

Precision:

The following table provides comparison data on the precision between the VARIANT II TURBO Link Hemoglobin A1c and VARIANT II TURBO Hemoglobin A1c Programs, each utilizing low and high EDTA whole blood patient samples, and both tested against samples with normal (6.0,6.2) and high (9.4,12.5) % A1c content.

Method precision was performed using a protocol based on the NCCLS Evaluation protocol, Vol.24, No. 25, EP5-A2 (2004) for the VARIANT II TURBO Link Hemoglobin A1c and VARIANT II TURBO Hemoglobin A1c Programs. The protocols for both the VARIANT II TURBO Link Hemoglobin A1c and VARIANT II TURBO Hemoglobin A1c Programs are similar.

Using these protocols, 40 runs (2 per day) were performed on one VARIANT II TURBO Link (or VARIANT II TURBO) Hemoglobin Testing System over 20 working days. In each duplicate daily run, one aliquot of normal and one aliquot of diabetic patient samples were each analyzed per run.

Although the precision samples are different, since they were run at different time periods, the precision results between the VARIANT II TURBO Link Hemoglobin A1c and the VARIANT II TURBO Hemoglobin A1c Program are equivalent. A summary of combined comparative precision results is presented in the following precision table.

VARIANT II TURBO Link Hemoglobin A1c and VARIANT II TURBO Hemoglobin A1c Precision

	VARIANT II TURBO Link Hemoglobin A1c Program		**VARIANT II TURBO Hemoglobin A1c Program**	
	Normal Patient (HbA_{1c})	**Diabetic Patient (HbA_{1c})**	**Normal Patient (HbA_{1c})**	**Diabetic Patient (HbA_{1c})**
n= (number of samples)	80	80	80	80
Mean	6.01	9.43	6.2	12.5
Within run (%CV)	0.62	0.47	0.82	0.54
Total Precision (%CV)	1.27	0.92	1.94	2.58

Linearity:

	VARIANT II TURBO Link Hemoglobin A1c Program	**VARIANT II TURBO Hemoglobin A1c Program**
Linear Range	4.1 – 17.6 % HbA1c	4.1 – 16.8 % HbA1c

Conclusion:

When considering the similarities of the intended use, the general characteristics of the two assays, the use of the same technology and the similar correlation, accuracy and linearity between the two methods, it can be concluded that the VARIANT II TURBO Link Hemoglobin A1c Program is substantially equivalent to the cleared and currently marketed predicate, VARIANT II TURBO Hemoglobin A_{1c} Program.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 25 2007

Bio-Rad Laboratories, Inc.
c/o Ms. Jackie H. Buckley
4000 Alfred Nobel Drive
Hercules, CA 94547

Re: k070819
Trade Name: Variant II Turbo Link Hemoglobin Testing System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, KRZ
Dated: March 23, 2007
Received: March 26, 2007

Dear Ms. Buckley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k070819

Device Name: VARIANT II TURBO Link Hemoglobin A1c Program

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Patricia Berglund (for Carol Benson)
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K070819